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SPECIFICATION FOR WARFARIN BAIT CONCENTRATES

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BUREAU OF INDIAN STANDARDS

MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG

NEW DELHI 110002

Gr 3 *August* 1970

Indian Standard

SPECIFICATION FOR WARFARIN BAIT CONCENTRATES

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AMENDMENT NO. 4 MAY 1994
TO
IS 5549 : 1970 SPECIFICATION FOR WARFARIN BAIT CONCENTRATES

(*Page* 5, *clause* **4.1**) — Substitute the following for the existing:

'When freshly manufactured material in bulk quantity is offered for inspection, representative samples of the material shall be drawn and tested as prescribed in IS 10627 : 1983 within 90 days of its manufacture. When the material is offered for inspection after 90 days of its manufacture, sampling shall be done as prescribed in IS 10627 : 1983. However, the criteria for conformity of the material when tested, shall be the limits of tolerances, as applicable over the declared nominal value and given under clause **2.2.1** of the standard'.

(FAD 1)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 5 AUGUST 2008
TO
IS 5549 : 1970 SPECIFICATION FOR WARFARIN BAIT CONCENTRATES

(*Page* 6, *clause* **A-3.1**) — Substitute the following for the existing text:

$$\text{'Material passing through 53-micron IS Sieve, percent by weight} = \frac{100\,(W - w)}{W}$$

where

w = weight in g of the material retained on the test sieve, and
W = weight in g of the material taken for the test.

(*Page* 11, *Table* 2, *col* 5) — Substitute ' $\bar{X}_1 - 0.6\,R_1 \geq 95$ percent' *for* ' $\bar{X}_1 - 06.\,R_1 \geq 95$ percent'.

(FAD 1)

Reprography Unit, BIS, New Delhi, India

Indian Standard

SPECIFICATION FOR WARFARIN BAIT CONCENTRATES

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 27 February 1970, after the draft finalized by the Pest Control Sectional Committee had been approved by the Agricultural and Food Products Division Council and the Chemical Division Council.

0.2 Warfarin bait concentrates are used in formulating rodent baits for the control of rodent pests in homes, fields and warehouses.

0.3 Taking into consideration the views of producers, consumers, testing authorities and technologists, the Sectional Committee responsible for the preparation of this standard felt that it should be related to the manufacturing and trade practices followed in the country in this field.

0.4 This standard is one of a series of Indian Standards on pesticides and their formulations.

0.5 This standard contains clauses **3.1**, **C-2.3** and **C-3.4** which call for an agreement between the purchaser and the vendor.

0.6 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements and the methods of test for warfarin bait concentrates used in the preparation of rodent baits.

2. REQUIREMENTS

2.1 Physical — The material shall conform to the following physical requirements.

---

*Rules for rounding off numerical values (*revised*).

2.1.1 *Description* — The material shall consist of technical warfarin compounded with talc or other suitable diluent, and shall be in the form of uniformly blended free-flowing powder, free from lumps and extraneous impurities which may limit its suitability for baiting rodents or impair its effectiveness. The technical warfarin used in the manufacture of the concentrates shall conform to IS : 5552-1970*.

2.1.2 *Sieving Requirement* — When tested by the method prescribed in Appendix A, not less than 95 percent by dry weight of the initial amount taken for the test, shall pass through 75-micron IS Sieve (*see* IS : 460-1962†).

2.2 Chemical — The material shall comply with the following chemical requirement.

2.2.1 *Warfarin Content* — When determined by the method prescribed in Appendix B, the observed warfarin content, percent by weight, of any of the samples shall not differ from the nominal value by more than the tolerance limits indicated below:

Sl No.	*Nominal Value, Percent*	*Tolerance Limit, Percent*	
i)	Up to 10	$^{+10}_{-5}$	of the nominal value
ii)	Above 10 and up to 50	± 5	,,
iii)	Above 50	$^{+5}_{-3}$	,,

2.2.1.1 The actual value of the technical material in the formulation shall be calculated to the second decimal place and then rounded off to the first decimal place before applying the tolerances given above.

3. PACKING AND MARKING

3.1 Packing — The material shall be packed in clean and dry air-tight containers made of galvanized steel sheet, tinplate, steel, glass, plastic or cardboard and polyethylene as agreed to between the purchaser and the manufacturer.

3.2 Marking — The containers shall be securely closed and sealed air-tight after filling them with the material, and shall bear legibly and indelibly the following information:

a) Common name of the material;

b) Name of the manufacturer;

---

*Specification for warfarin technical.

†Specification for test sieves (*revised*).

c) Date of manufacture;

d) Batch number;

e) Net weight of the contents;

f) Warfarin, technical, percent content by weight;

g) The word 'POISON' in distinct, bold capital letters, in red; and

h) The minimum cautionary notice worded as under:

> 'HAZARDOUS. KEEP THE MATERIAL AND BAITS CONTAINING THE MATERIAL AWAY FROM CHILDREN, DOMESTIC ANIMALS, FOODSTUFFS, ANIMAL FEEDS. DO NOT USE THE EMPTY CONTAINER FOR STORAGE OF FOODSTUFFS OR FEEDS.
>
> ANTIDOTE: MASSIVE DOSES OF VITAMIN K AND IF FOUND NECESSARY BLOOD MAY BE TRANSFUSED'.

3.2.1 The containers may also be marked with the Certification Mark.

NOTE — The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or processors, may be obtained from the Bureau of Indian Standards.

4. SAMPLING

4.1 The method of drawing representative samples of the material and the criteria for conformity shall be as prescribed in Appendix C.

5. TESTS

5.1 Tests shall be carried out by the appropriate methods referred to in **2.1.2** and **2.2.1**.

5.2 Quality of Reagents — Unless specified otherwise, pure chemicals and distilled water (*see* IS : 1070-1960*) shall be employed in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

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*Specification for water, distilled quality (*revised*).

APPENDIX A

(*Clause* 2.1.2)

TEST FOR SIEVING REQUIREMENT

A-1. APPARATUS

A-1.1 Test Sieve — 75-micron IS Sieve (*see* IS : 460-1962*), prepared for test by removing any film, grease or other water-repellent material and then drying.

A-2. METHOD

A-2.1 Weigh accurately 100 g of the material and transfer it to the test sieve. Cover the sieve and screen the material in a suitable sieve vibrator for 10 minutes. Two small square rubber cubes are introduced along with the material on the sieve to facilitate the breaking up of any soft lumps of the caked material. After 10 minutes, stop the machine and brush the residue on the sieve into a tared weighing dish. Weigh the dish and determine the weight of the residue.

A-3.CALCULATION

A-3.1 Material passing through 53-micron IS Sieve, percent by weight $= \frac{100 (1 - w)}{W}$

where

w = weight in g of the material retained on the test sieve, and

W = weight in g of the material taken for the test.

APPENDIX B

(*Clause* 2.2.1)

DETERMINATION OF ACTIVE INGREDIENT CONTENT

B-1. APPARATUS

B-1.1 Spectrophotometer — Beckman, model DU, or equivalent instruments with 1-cm quartz cells.

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*Specification for test sieves (*revised*).

B-2. REAGENTS

B-2.1 Reference Solution — Prepare by pipetting 2 ml of ethylene dichloride into a glass stoppered cylinder, adding 10 ml of one percent sodium hydroxide solution with a pipette, and shaking for one minute. The sodium hydroxide layer is decanted into a centrifuge tube and centrifuging until it becomes clear.

B-3. PROCDURE

B-3.1 weigh accurately about 600 mg of the sample into a 125-ml glass stoppered flask, add 50 ml of ethylene dichloride with a pipette, place the flask on a shaking machine and shake for at least 10 minutes. Transfer the contents to a centrifuge tube, stopper and centrifuge at high speed for 5 minutes or until clear. Pipette 2 ml of ethylene dichloride extract into a glass stoppered cylinder, add 10 ml of one percent sodium hydroxide solution with a pipette, and shake by hand for 1 minute. Decant the sodium hydroxide layer into a centrifuge tube and centrifuge until clear. Pipette a sufficient amount (about 3 ml) of the alkali layer into 1-cm quartz cell and, with the spectrophotometer set at maximum sensitivity determine its absorption (*see* Note) at 308 nm (nanometre) against the reference solution.

NOTE — For routine testing it is necessary to have a standard curve down and compared with the test sample.

B-4. CALCULATION

B-4.1 Molecular weight of warfarin = 308·3

Molar extinction coefficient = $1{\cdot}42 \times 10^4$

[Molar extinction coefficient shall be determined with pure 3-(alpha-phenyl-beta-acetylethyl)-4-hydroxycoumarin; the value given here is an example only.]

$$\text{3-(alpha-phenyl-beta-acetylethyl)-4-hydroxycoumarin, percent content (warfarin)} = \frac{E \times 308{\cdot}3 \times 10 \times 50 \times 100}{1{\cdot}42 \times 10\,000 \times 1\,000 \times 2 \times W} = \frac{E \times 0{\cdot}54}{W}$$

where

E = absorption of the final solution at 308 nm, and

W = weight in g of the sample.

APPENDIX C

(*Clause* 4.1)

SAMPLING OF WARFARIN BAIT CONCENTRATES

C-1. GENERAL PRECAUTIONS

C-1.0 In drawing, preparing, storing and handling test samples, the following precautions and directions shall be observed.

C-1.1 Samples shall not be taken in an exposed place.

C-1.2 The sampling instrument shall be clean and dry when used.

C-1.3 Proper precautions shall be taken while drawing samples since the material is poisonous.

C-1.4 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the receptacles for samples from adventitious contamination.

C-1.5 The samples shall be placed in suitable, clean, dry, and air-tight sample receptacles. The samples shall be protected from light.

C-1.6 The sample receptacles shall be of such a size that they are almost, but not completely, filled by the sample.

C-1.7 Each sample receptacles shall be sealed air-tight after filling and marked with full details of sampling, the date of manufacture, name of the manufacturer and other particulars of the consignment.

C-1.8 Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

C-2. SCALE OF SAMPLING

C-2.1 Lot — All the containers in single consignment of the material drawn from the same batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

C-2.1.1 Samples shall be tested for each lot for ascertaining the conformity of the material to the requirements of this specification.

C-2.2 The number of containers to be chosen from the lot shall depend on the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 NUMBER OF CONTAINERS TO BE CHOSEN FOR SAMPLING

LOT SIZE N	NO. OF CONTAINERS TO BE CHOSEN n
(1)	(2)
3 to 15	3
16 to 40	4
41 to 65	5
66 to 110	7
Over 110	10

C-2.3 These containers shall be chosen at random from the lot. In order to ensure the randommess of selection, some random number table, as agreed to between the purchaser and the vendor, shall be used. In case such a table is not available, the following procedure shall be adopted:

> Starting from any container in the lot, count them as 1, 2, 3,..... etc, up to r, in a systematic manner where r is equal to the integral part of the value of N/n, N being the total number of containers in the lot and n the number of containers to be chosen (*see* Table 1). Every rth container thus counted shall be separated until the requisite number of containers is obtained from the lot to give samples for test.

C-3. TEST SAMPLES AND REFEREE SAMPLES

C-3.1 Before drawing the test sample, mix thoroughly the contents of each container selected, by shaking or by any other suitable means so as to bring all portions into uniform distribution. Draw small portions of the material from different parts of each container selected (*see* Table 1). The total quantity of the material drawn from each container shall be not less than 750 g.

C-3.2 Mix thoroughly all the material drawn from the same container. A small but equal quantity shall be taken from each selected container and shall be well mixed together so as to form a sample of not less than 100 g. This sample shall be divided into three equal composite test samples, one for the purchaser, another for the vendor, and the third for the referee.

C-3.3 The remaining material drawn from a container (after the quantity needed for formation of the composite test samples has been taken out) shall be divided into three equal parts. These parts shall be immediately transferred separately to thoroughly dried sample receptacles which are then sealed air-tight, and labelled with all the particulars of sampling given under **C-1.7**. The material in each such sealed sample receptacle shall constitute an individual test sample. These individual test samples shall be separated into three identical sets of individual test samples in such a way that each set has a sample representing each container selected (*see* Table 1). One of these three sets shall be marked for the purchaser, another for the vendor, and the third for the referee.

C-3.4 Referee Samples — Referee samples shall consist of one of the composite test samples (*see* **C-3.2**) and a set of individual test samples (*see* **C-3.3**) marked for this purpose and shall bear the seals of the purchaser and the vendor. These shall be kept at a place agreed to between the two.

C-4. TESTING OF SAMPLES

C-4.0 The number of tests mentioned in **C-4.1** and **C-4.2** shall be first conducted on the test samples marked for the purchaser. In the contingencies, such as loss, spoilage, spilling, etc, of the purchaser's test samples or if the vendor so desires, the test samples marked for the vendor may be tested. In case of a dispute, the referee test samples shall be tested and the test results obtained on the referee test samples shall be considered as final.

C-4.1 Tests for the determination of warfarin content shall be conducted on each of the individual test samples (**C-3.3**).

C-4.2 Tests for the determination of the remaining characteristic, namely, the sieving requirement, material passing through 53-micron IS Sieve, shall be conducted on the composite test sample as prepared under **C-3.2**.

C-5. CRITERIA OF CONFORMITY

C-5.1 A lot shall be declared as conforming to the specification, when:

a) each of the test results for warfarin content satisfies the requirement specified in **2.2.1**. If, however, one or more of the test results do not satisfy the specified requirement, the conformity of the lot shall be ascertained in accordance with **C-5.1.1**; and

b) the test results on the composite sample for sieving requirement, material passing through IS Sieve 75, satisfy the corresponding requirement given in **2.1.2**.

C-5.1.1 In case one or more of the test results do not satisfy the requirement for warfarin content, the following procedure shall be adopted for determining conformity of the material in respect of this characteristic.

The mean and the range of the corresponding test results shall be calculated as:

$$\text{Mean } (\bar{X}_1) = \frac{\text{The sum of the test results}}{\text{Number of test results}}$$

Range (R_1) = The difference between the highest and the lowest value obtained for the test results.

The appropriate expression as shown in col 5 of Table 2 shall be calculated. If the value of this expression satisfies the relevant condition given in col 5 of Table 2, the lot shall be declared to have satisfied the requirement for warfarin content.

TABLE 2 CRITERION FOR CONFORMITY

CHARACTERISTIC	TEST RESULTS	MEAN	RANGE	CRITERION FOR CONFORMITY
(1)	(2)	(3)	(4)	(5)
Warfarin content, percent by weight	1, 2, 3, ... n	$\bar{X}_1$	R_1	$\bar{X}_1 - 06{\cdot}R_1 \geqslant 95$ percent of the value as declared on the container
				$\bar{X}_1 + 0{\cdot}6R_1 \leqslant 105$ percent of the value as declared on the container

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